April 16, 2001. The Examiner maintains her belief that the specification does not support the limitation of immediate storage tube location with an associated alert mechanism for identifying when the immediate sample is loaded into the system as recited by claims 11 and 24. In particular, the Examiner notes that the reply to the previous Office Action is not persuasive because the pages cited by applicants in support of their argument are not correct. In response, applicants corrected typographical errors in the cited page and line numbers as shown in bold below.

The specification teaches that the clinical chemistry system of the present invention provides a predetermined number of immediate or STAT tube locations 36 for more immediate testing, which allows to bypass what may be as many as two hundred samples queued in the system (page 10, **lines 14-17**). The specification also teaches that the system of the present invention includes a STAT button 38 that, when manually pressed, alerts the system that there are sample tubes in STAT positions that must be accessed (**page 10, lines 17-24**). Therefore, the specification sufficiently describes the alert mechanism of claims 11 and 24.

In the Office Action dated August 22, 2001, claims 20-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 20 is rejected due to the use of the word "it" and because the term "the sample identification station" lacks proper antecedent basis. In response, applicants have amended claim 20 to address the Examiner's objections.

In the Office Action dated August 22, 2001, claims 1-11 and 13-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al.* (U.S. Patent No. 5,350,564) in view of Kodama *et al.* (U.S. Patent No. 6,117,683). This rejection is respectfully traversed.

Both independent claims 1 and 20 require a carriage mechanism that <u>grips and transports</u> a primary sample tube. More particularly, the carriage mechanism of claim 1 grips one of a plurality of primary sample tubes stored in a storing station, transports the sample tube to the sampling station, and then <u>returns</u> the

primary sample tube <u>to the storing station</u>. Claim 1 has been amended to clarify that the carriage mechanism of the present invention returns the primary sample tube directly from the sampling station to the storing station. The support for this amendment can be found on page 11, lines 1-10.

Because the instant carriage mechanism operates in a "grip and transport" mode and because it transports individual sample tubes, samples stored in the storing station can be accessed in any order and can be subjected to different testing protocols. For example, one sample may be subjected to a single test, while another can be tested by a series of analyzers. Due to the flexibility of the sample access provided in the present invention, any sample contained in the storing station can be repeatedly accessed to verify test results or to conduct a different type of testing (page 5, line 13, - page 6, line 2). Additionally, because in the present invention individual sample tubes are gripped and transported to the sampling station, the carriage mechanism can access samples contained in a random assortment of different size and type tubes (page 10, lines 5-9).

Claim 20 has been amended to clarify that when the carriage mechanism <u>grips</u> the primary sample tube contained in a holder, the primary sample tube <u>separates</u> from the holder. The support for this amendment can be found on page 11, lines 1-10, and in Figures 2 and 6. For example, as explained on page 11, lines 1-10, and shown in Figure 2, the gripper 40 grips and lifts successive sample tubes from the trays 32. The gripper then transports individual tubes to the sampling station. After the desired number of aliquots is drawn, the sample tube is returned to the tray and a next sample tube is accessed. As shown in Figure 6 and explained on page 15, lines 3-14, sampling station may include a tube spinner 120, which holds and rotates an individual sample tube 44 to expose the bar code to the bar code reader.

— No holder in Claim 1

The Mazza reference does not teach or suggest a carriage mechanism that returns a sample tube directly from the sampling station to the storing station. Neither does the Mazza reference teach or suggest a carriage mechanism that grips a sample tube, whereby the sample tube separates from its holder. Instead, the

— Not in Claim 20 carriage mech disclosed as gripping the primary tube & trans-ports it to sample station

\\\LA - 81841/19 - #118597 v2

Mazza reference describes an automatic chemical analyzer that utilizes interlocking carrier members for storing and transporting individual sample tubes in one direction, from an on-loading area to an off-loading area.

In the Mazza reference, the samples are manually loaded into carriers positioned within an on-loading area. Then the carriers are pushed from the on-loading area into a loading chute, and then into receptacles of a conveyor. Once the carriers are pushed into the loading chute, they <u>cannot be returned back</u> to the on-loading area without interrupting the testing cycle and/or without manual handling of the carriers. At the end of the testing cycle, the carriers are discharged into an off-loading tray. The sample tubes are then either discarded or stored in their carriers. When the sample tube are discarded, the carriers are reassembled and new sample tubes are loaded into the carriers. Then, the carriers with the new tubes are manually placed on the on-loading area (column 6, lines 7-42). Therefore, in the Mazza reference, sample tubes are not returned to the on-loading area at all and the carriers are returned to the on-loading areas manually and only after the testing cycle is completed. Accordingly, the Mazza reference, does not teach or suggest a carriage mechanism that returns a sample tube directly from the sampling station to the storing station.

Also, the analyzer of Mazza <u>cannot handle tubes separately from their carriers</u>. Once a sample tube is placed into a carrier, the tube stays in the carrier throughout the testing. When testing of the sample is completed, the carrier is removed from the conveyor onto an off-loading station. At that time, a sample tube may be manually removed from the carrier (column 6, lines 7-42).

In this regard, applicants respectfully draw the Examiner's attention to Figures 1 and 3A of the Mazza reference for a more detailed discussion of the operation of Mazza's analyzer. Initially, plural interlocked ranks **18** of sample tube carriers are arranged on an on-loading area **12** so that individual sample tube carriers in the ranks align to form forwardly-extending files **20** (column 7, lines 32-39). The <u>on-loading area</u> **12** includes a number of pushing mechanisms that slide sample tube carriers along predetermined passages. The pushing mechanisms

are used "for slidably advancing the sample tube carriers **16**; for laterally sliding the carriers out of their que **14** of the stat line, or out of files **20**, and into alignment with a loading chute **22**; for slidably advancing the carriers individually along the loading chute **22**" onto turntable **226** for sample identification by bar code reader **234**; "and for slidably advancing the individual sample tube carriers **16** further along the loading chute **22** and into an individual aligned receptacle **32** of ... endless loop conveyor **34**" (column 7, lines 40-62, and column 15, lines 60-68). Thus, the carriers of Mazza are not gripped and lifted to be placed in a desired location, but rather slided along a predetermined pass.

The endless loop conveyor **34** transports the samples to at least one chemical analysis module. Carriers with tested samples are discharged from the endless loop conveyor device into an off-loading tray **56** which again interlocks the carriers and presents them in rank and file groups for subsequent handling (abstract, column 5, lines 45-55). Sample tubes remain in the carriers from the beginning of the testing, when the sample tubes are placed into the carriers, to the end of the testing, when the carriers are discharged into an off-loading tray. Therefore, in the Mazza reference, at no time during testing cycle do the sample tubes separate from their holders. Accordingly, the Mazza reference does not teach or suggest a carriage mechanism that grips a sample tube, whereby the sample tube separates from its holder, and transports the tube to the sample identification station, as required by the instant claim 20.

Also, the analyzer of Mazza accommodates only the forward advancement of the carriers. For example, once the carrier is pushed onto the turntable **226** and the sample bar code is read by the bar code reader **234**, the pusher pad **224** engages the carrier and moves it along and out of the loading chute into the loading receptacle **32** of the conveyor **34** (column 15, line 60, - column 16, line 32). Accordingly, the carrier with the sample tube cannot immediately return back to the on-loading area **12**. Therefore, the Mazza reference does not teach or suggest a carriage mechanism that grips a sample tube, transports the tube to a sample identification station, and then returns it to the storing station, as required by the instant claim 1.

Finally, the analyzer of Mazza is constructed to maintain rank and file of each sample during transport of the samples (column 4, lines 7-31). Additionally, as explained above, the analyzer of Mazza allows only forward advancing of the samples by sliding their carriers through the loading chute. As a result of such an arrangement, the analyzer of Mazza does not allow an automatic and random access to sample tubes positioned in the on-loading sample area. The present invention unexpectedly overcomes this disadvantage by providing a more flexible carriage mechanism, which grips and picks up sample tubes from the storing station in any desired order. Thus, contrary to the Examiner's belief, the Mazza reference does not teach or suggest the carriage mechanism of either instant claim 1 or 20.

The Kodama reference cannot remedy the defect of the Mazza reference, and is not relied upon by the Examiner for such. The Kodama reference has no teaching whatsoever of moving an individual primary sample tube, much less of the carriage mechanism that grips and transports a primary sample tube to the sampling station and then returns the primary sample tube to the storing station, as required by the instant claim 1. Neither does the Kodama reference teach or suggest a carriage mechanism that grips a sample tube, whereby the sample tube separates from its holder, and transports the tube to the sample identification station, as required by the instant claim 20.

Instead, the Kodama reference teaches a transfer mechanism for transferring sample racks **9** with sample vessels **76** from rack trays **11** and **12** to rack trays **20** and **21**. As shown in Figure 2 of the Kodama reference, the racks are advanced in a forward direction by a system including a hook device **8** and conveyance path **6**, main conveyance line **13**, and conveyance path **7** with pushing devices **23** and **24** (columns 4-5). A plurality of analysis units **100** and **200** are arranged along the main conveyance line 13. The racks may be transferred by transfer mechanisms **15a**, **15b**, **19a**, and **19b** to and from sample transfer areas **71** and **72** of the analysis units (column 6, lines 5-31). In the sample transfer areas, the contents of the samples are delivered from the sample tubes to reaction vessels by a sample

delivery device **204** (column 8, lines 45-65). After the samples are delivered from the sample tubes, the racks holding the sample tubes are transferred back to the main conveyance line **13** and ultimately the racks are transported to the off-loading trays **20** and **21**. Nowhere in the Kodama analyzer do the sample tubes separate from their holding racks. Therefore, nothing in the Kodama reference teaches or suggests a carriage mechanism that <u>grips</u> a sample tube, whereby the sample tube <u>separates from its holder</u>, and transports the tube to the sample identification station, as required by the instant claim 20.

Also, the Kodama reference teaches moving sample tubes in the racks in one direction only. Accordingly, once a rack holding the sample tubes is pushed onto the conveyance line **13** and then sample transfer area **71** or **72**, the rack will continue forward until it reaches off-loading trays **20** and **21** and cannot automatically return to the on-loading trays **11** and **12**. Thus, nothing in the Kodama reference teaches or suggests a carriage mechanism that <u>grips</u> a sample tube, transports the tube to a sample identification station, and then <u>returns</u> it to the storing station, as required by the instant claim 1.

Furthermore, it would not have been obvious to combine the two references, because such a combination is not possible without significant modifications to the Mazza system.

Mazza describes an automatic chemical analyzer that utilizes interlocking carrier members for storing and transporting individual sample tubes (abstract and column 7, lines 19-39). The carrier members must be <u>unlocked and loaded one-by-one</u> onto a rotator assembly for bar code reading (column 7, lines 40-62). In the Kodama reference, on the other hand, conventional, non-modular sample <u>racks</u> are used to transport sample tubes within the automatic analyzer. In order to combine Mazza and Kodama as suggested by the Examiner, one would have to completely redesign Mazza's analyzer, which uses modular locking/unlocking individual sample tube carriers, to accommodate the tube racks of Kodama. Such a modification is not possible without destroying the function of the analyzer disclosed in Mazza. It is

respectfully submitted, therefore, that it would be unobvious to combine Mazza and Kodama to arrive at the present invention.

Additionally, there is no suggestion in the cited references of modifying the analyzers disclosed therein in the direction of the present invention, nor is there any suggestion whatsoever of the desirability of such a modification. The mere fact that a reference may be modified in the direction of the claimed invention does not make the modification obvious unless the reference expressly or impliedly teaches or suggests the desirability of the modification. Thus, it is respectfully submitted that the ordinarily skilled artisan, working without the benefit of the applicant's specification, would have had no motivation to combine the features of the cited references to arrive at the present claims 1 and 20. Therefore, claims 1 and 20 are neither anticipated nor rendered obvious by the Mazza and Kodama references, either alone or in combination. Claims 2-19 and 21-34 depend, directly or indirectly, from patentable claims 1 and 20 and are, therefore, believed to be patentable for at least the same reasons as claims 1 and 20.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza *et al.* (U.S. Patent No. 5,350,564) and Kodama *et al.* (U.S. Patent No. 6,117,683) as applied to claim 10, and further in view of Kurosaki *et al.* (U.S. Patent No. 5,587,129). This rejection is respectfully traversed.

The Kurosaki reference, cited against claim 12, does not address the deficiencies of the Mazza and Kodama references. Kurosaki is relied on for teaching a cap piercer, and it does not teach a "carriage mechanism that grips one of the plurality of primary sample tubes," as required by claim 1. Therefore, claim 1, as well as claim 12 that depends therefrom, is patentable over the Mazza, Kodama, and Kurosaki references, either alone or in any combination.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the

Los Angeles, California telephone number (213) 337-6700 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
HOGAN & HARTSON L.L.P.

Date: October 22, 2001

By:______________________
Wei-Ning Yang
Registration No. 38,690
Attorney for Applicant(s)

500 South Grand Avenue, Suite 1900
Los Angeles, California 90071
Phone: 213-337-6700
Fax: 213-337-6701

\\\LA - 81841/19 - #118597 v2

<u>Version with markings to show changes made:</u>

Please replace the text of claims 1 and 20 with the following text:

1. (Twice Amended) A clinical chemistry system comprising:

a storing station that receives and stores a plurality of primary sample tubes;

a sampling station including a sample probe that draws a volume of sample from a primary sample tube and transfers the volume to a secondary tube;

a carriage mechanism that grips one of the plurality of primary sample tubes and transports the primary sample tube to the sampling station and returns the primary sample tube <u>from the sampling station</u> to the storing station;

a first and a second secondary tube transfer station, respectively, for coupling to first and second analyzers, the first and second sample tube transfer stations adapted to move the secondary sample tube from a continuous transport mechanism to be received by a corresponding one of the first and second analyzers; and

the continuous transport mechanism for moving filled secondary tubes to a selected one of the first and second secondary tube transfer stations.

20. (Twice Amended) A clinical chemistry system comprising:

a sample identification <u>station comprising a sample identification</u> mechanism for determining sample identification information from a primary sample tube;

a transferring mechanism for transferring a volume of the sample from the primary sample tube into a secondary sample tube;

a carriage mechanism that grips the primary sample tube <u>contained in a holder, whereby the primary sample tube separates from the holder,</u> and transports [it] <u>the primary sample tube</u> to the sample identification station;

a continuous transport mechanism for moving secondary sample tubes within the system;

first and second sample tube transfer stations, respectively, for coupling to first and second analyzers, the first and second sample tube transfer stations

adapted to move the secondary sample tube from the continuous transport mechanism to an interface of a first or second analyzer; and

a host computer, the host computer receiving sample identification information and issuing a sample testing message that includes one of the first and second analyzers as a destination.